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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,548	10/14/2003	Jeffrey S. Bauer	6122-66637	3478

24197 7590 10/18/2005  
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PORTLAND, OR 97204

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/686,548	<b>Applicant(s)</b> BAUER ET AL.	
	<b>Examiner</b> Gary W. Counts	<b>Art Unit</b> 1641	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

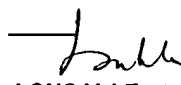
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: NONE.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-29, 31, 35-38, 40-45, 47, 49.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

  
**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

*10/18/05*

Continuation of 11 NOTE:

**Rejection withdrawn**

The 112 2<sup>nd</sup> rejections of claims 4, 6, 20, 21 and 31 are withdrawn. Applicant's amendment to the claims and arguments are found persuasive therefore, the 112 2<sup>nd</sup> rejections are withdrawn.

With respect to the terminal disclaimer the rejections of claims 5-9 under the judicially created doctrine of obviousness-type double patenting is withdrawn. Applicant's arguments are found persuasive for claims 5-9. However, the remaining claims are still rejected under obviousness-type double patenting. See arguments below concerning the rejection.

**103 Rejections**

Applicant argues that the rejection in view of the alleged inherent disclosure of Boehringer et al. is improper because Applicants have already shown that Boehringer et al. does not necessarily disclose an assay in which sequential migration of the analyte and tracer occurs. Applicant states that the specification at page 21 explains that sequential migration of the analyte and tracer is the result of a specific combination of tracer complexes, pore size, binding partners and other factors that permit separation of the wave fronts in which the analyte and tracer migrate. As proven in the Declaration of Buck submitted with Applicants' prior response, it is quite possible for the detectable trace and analyte to reach the primary capture zone together for example if the detectable tracer does not migrate a distance sufficient for separation of the wave fronts

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to occur. Applicant further states that the cited reference does not necessarily satisfy the claim limitation that " the detectable tracer is present on the test strip in a position that a distal flow of analyte reaches the primary capture area before the distal flow of tracer reaches the primary capture area". This is not found persuasive because as stated in the previous office action the declaration is not commensurate with the scope of the claims. Nowhere in the claims is a recitation of distance between the zones.

Further, Applicant has not shown why the distance of the tracer zone from the primary capture zone of the current application is better than that of Boehringer et al.

Boehringer et al shows that the tracer zone is located at a distance from the primary capture area (see figure 1). Further, Boehringer et al meets all the structural limitations of the claim including using particles which are even larger than Applicants and coated with the same material Applicant uses (BSA, specification page 20, lines 26-31, which states that BSA causes the molecule to migrate more slowly). Boehringer et al disclose the mobilization zone, mobile or mobilizable detectable tracer in the mobilization zone, sample application primary and secondary capture areas with the same reagents as Applicant and also discloses them in the same order as claimed by Applicant. Further, as stated above Boehringer shows that the tracer zone is located at a distance from the primary capture area. Therefore, since Boehringer teaches the same materials in the same order Boehringer would achieve the separation of wave fronts that allows the analyte to reach the primary capture zone first. Applicant has not recited anything different than that of the prior art.

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Applicant argues that Boehringer et al. describes the prior art problem that Applicant's currently claimed invention was designed to overcome, namely the loss of sensitivity caused by the competitive instead of sequential interaction of the analyte and labeled tracer in the primary capture zone. This is not found persuasive because as stated above Applicant has not recited anything different than what the prior art teaches. Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Dd. Pat. App. & Inter. 1985).

Applicant argues that claim 3 calls for the tracer to be heavier than the analyte, and there is no discussion in the Office action or Boehringer et al reference about relative weights of the tracer and analyte. This is not found persuasive because as stated above Boehringer et al teaches that the detectable tracer can be an analyte analog of the analyte and that the detectable tracer also comprises microparticles coated with BSA. Therefore, one of ordinary skill in the art would recognize that the detectable tracer would weigh more than the analyte. Applicant further argues that Claim 4 calls for the tracer to be selected to interact with the test strip to slow its migration relative to the analyte. Once again, since Boehringer et al teaches the same detectable tracer and components of the test strip, the detectable tracer would interact and move slower (see also specification p. 20 concerning migration rate using BSA). Applicant further argues that Claim 5 concerns relative sizes and their relation to the bibulous strip, a subject which the references and Office action are also silent. This is

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not found persuasive because of reasons stated above. Further, the particles of Boehringer et al are even larger than that of the Applicant and the pore size of the bibulous membrane can be 1000 to 20,000 nm.

With respect to claims 2, 6 and 7 Applicant argues that the teachings of Fredrickson is the antithesis of the present invention, in that it teaches the use of submerged conjugate to achieve conjoined move of the analyte and conjugate, whereas the claimed invention specifically requires that the detectable tracer is position within the test strip in a position that the distal flow of tracer reaches the primary capture area after the distal flow of analyte. This is not found persuasive because the Examiner has not relied upon using the reagents of Fredrickson as it appears to be suggested by Applicant, but rather the Examiner merely depends on Frederickson for teaching that it is known within the art to impregnate a test strip with reagents. Therefore, it would have been obvious to one of ordinary skill in the art to impregnate the detectable tracer of Boehringer et al as taught by Frederickson.

Applicant argues that because the office action has disregarded the claim limitation of claim 7 that the tracer is selected based on its polarity and charge to provide specific migration of the analyte and that the cited references are completely silent about selecting such a particle based on its interaction with the test strip. Applicant states that since none of the cited references disclose or suggest that the polarity or charge be selected based on an interaction with the test strip, a prima facie case of obviousness has not been met. This is not found persuasive because the instantly recited claims are directed to a test strip and it appears that all limitations of the strip have been met.

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Further, the recitation "is selected" appears to be a method step of making the test strip and therefore does not further limit the structure of the test strip. Further, since Boehringer et al use the same detectable tracer as disclosed by applicant the detectable tracer of Boehringer et al would provide polarity or charge which provides specific migration characteristics that retard migration of the tracer relative to migration of the analyte.

With respect to claim 14 Applicant argues that Leuvering provides a rote list of different modes of attachment which are considered equivalent and a prima facie case of obviousness is not established by citing to a long list of species and contending that it would be obvious to select a particular species from the list of possibilities. This is not found persuasive because as stated in the previous office action Boehringer et al makes specific reference to the labeling and labeling techniques of Leuvering (page 34, lines 21-37 of Leuvering). Further, it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills*, 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

With respect to claims 8 and 9 Applicant argues that claims 8 and 9 depend from claim 7 which is allowable. This is not found persuasive because of reasons above concerning claim 7. Applicant further states that the rejection relies on hindsight reconstruction of the claimed invention in view of the Applicants' own disclosure. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning.

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But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With respect to claims 22-24, 26 and 29 Applicant argues that the rejection assumes that there is some teaching in the prior art that sequential migration of the analyte and tracer occurs. Applicant states that the theory of operation of Boehringer et al. is set forth at page 16, lines 36-38 as being that the labeled analyte analog "competes effectively for binding at the downstream capture" and that this differs from the claimed sequential migration of claim 22 in which the "flow of analyte reaches the primary capture area before the tracer such that subsequent binding of tracer to the first antibody is inhibited and unbound tracer continues along the path of flow to the second antibody to provide a signal..." This is not found persuasive because Boehringer et al meets all the structural limitations of the claim including using particles which are even larger than Applicants and coated with the same material Applicant uses (BSA, specification page 20, lines 26-31, which states that BSA causes the molecule to migrate more slowly). Boehringer et al disclose the mobilization zone, mobile or mobilizable detectable tracer in the mobilization zone, sample application primary and secondary capture areas with the same reagents as Applicant and also discloses them in the same order as claimed by Applicant. Further, as stated above Boehringer shows that the tracer zone is located at a distance from the primary capture area. Therefore, since Boehringer teaches the same materials in the same order Boehringer achieve the



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separation of wave fronts that allows the analyte to reach the primary capture zone first.

Applicant has not recited anything different than that of the prior art.

Applicant argues that claim 24 specifically notes that the tracer is selected so that a diameter of the tracer is small enough to migrate through the bibulous test strip but not so large that it is trapped by pores of the bibulous strip. This is not found persuasive because as stated in the previous office action the pore size of the bibulous membrane can be 1000 to 20,000 nm. And one of ordinary skill in the art would recognize that this pore size is larger than that of the particles listed in Boehringer et al and therefore is capable of allowing the tracer to migrate through the bibulous test strip but not so large that it is trapped by the pores.

**Terminal Disclaimer**

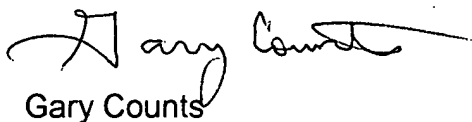
With respect to the terminal disclaimer Applicant argues that it is not accurate to assert that the claims from the '722 patent would have encompassed the claims of the pending application Claims 1-4, 10-29, 31, 35-38, 40-45, 47 and 49. Applicant argues that there are many embodiments encompassed by the pending claims in which the tracer does not have a weight greater than the analyte for example, different size or polarity. This is not found persuasive for the above listed claims because for example claims 1 and 22 are broader than the claims of '722 patent which requires the tracer have a weight greater than the analyte. And one of ordinary skill in the art would recognize that the more narrow claims of '722 would encompass the broader claims listed above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art unit 1641  
October 7, 2005